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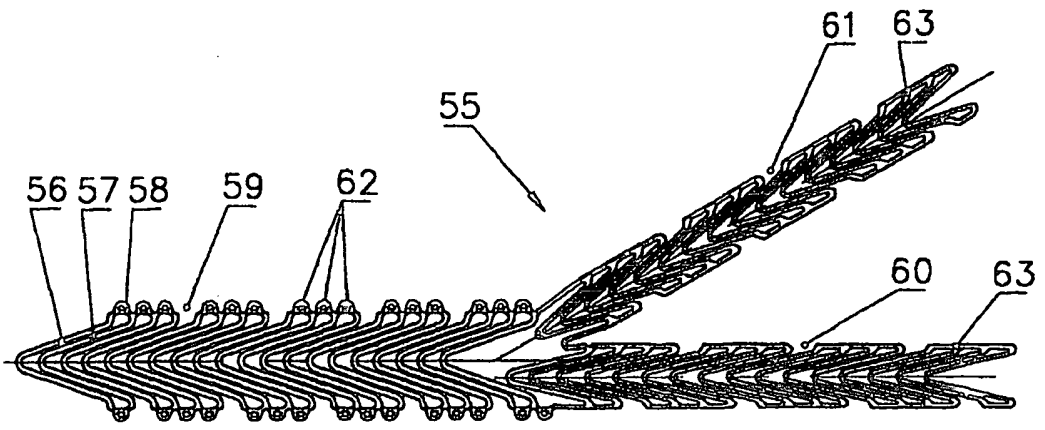

(57) Abstract

A single Y-shaped stent design is obtained, the constructive elements of which are preliminarily formed as a stencil on a thin metallic sheet surface. Stent (55), being located on two uninflated kissing ballons of a guiding catheter, has a minimal outward diameter size, and due to the proposed algorithmic connection of the closed loops (56, 57) by protrusions (58) of relatively rigid bands, which allow granting the stent longitudinal flexibility directly in places determined by the anatomical peculiarities of bifurcation segments. The stent secures a possibility of coating the bifurcation carina area with metal that should contribute to the more effective treatment of the lesion in that vessel part and to the generally more favorable outcome of intravascular intervention.

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THE SHEET EXPANDABLE TROUSERS STENT AND DEVICE FOR ITS IMPLANTATION

Field and Background

The invention discussed herein relates generally to medical technology, specifically to expandable cardiovascular stents, which are used for the radical recovery of arterial lumina with subsequent restoration of normal blood flow. In the present application, the term "stent" refers to a device employed to expand a blood vessel and to maintain the achieved size of the lumen. Conventionally, stents are delivered to the target area in the cardiovascular system on an inflatable balloon, located on the tip of a transluminal catheter. Upon reaching the target site, the balloon is inflated leading to the expansion of the stent thereby widening the lumen of the vessel. Other, less common stent delivery systems also exist.

Currently, stenting of bifurcation segments of coronary vessels remains a long, complicated and expensive procedure. Several techniques of coronary stenting have been developed in an attempt to facilitate this procedure (Di Mario and Colombo: "Trousers-Stents: How to Choose the Right Size and Shape?" Catheterization and Cardiovascular Diagnosis 41:197-199, 1997).

The most widely used method is "T" stenting, when two mesh stents are used to cover the bifurcation area (Fig. 1, pos 1, 2, 3, 4) of the treated coronary vessel. In this procedure, two guide wires (5, 6) are introduced into one of the major coronary arteries, for example, proximal LAD (2) and into a smaller vessel, for example diagonal D (3). Then, two kissing balloons are placed across the bifurcation area and predilation of the bifurcation is performed. Then, a stent (7) is delivered to the target area and deployed in the LAD. At this point, there are two variations of the procedure: 1) to leave the guide wire (6) in the side branch during stenting of the main artery (1) to facilitate the recrossing of the branch; or alternatively 2) to withdraw the wire to avoid additional vessel wall injury, when the wire (6) is forced into the vessel wall by the second stent (7). Accordingly, the advantage of either of the variations is the unavoidable disadvantage of the other. Then, another guidewire (8) is advanced through the stent wall into the side branch. This step requires a very experienced invasive cardiologist, since the wire has to

find its way throught the stent struts. To facilitate this step, for example, the average cell diameter in the NIR stent was nearly doubled. Still, crossing the stent with the wire remains a cumbersome procedure that cannot be successfully performed in all cases. Then, the second stent (9) is advanced to the side branch and deployed. There are certain technical maneuvers used to facilitate the placement of the second stent. For example, the balloon previously used for predilation of the branch, is advanced and inflated through the stent (7) into the branch to widen the stent cell diameter through which a second stent (9) will be introduced. Another important flaw of the technique is the complicated positioning of the second stent, which in many cases leads to either gaps at the carina (4) or protrusion of the side branch stent into the main vessel.

"T" stenting is successful in many cases and remains the primary method of stenting coronary artery bifurcations, especially of the large vessels (>3.0 mm). However, due to the disadvantages mentioned above it continues to be a cumbersome procedure with hampered long-term clinical results.

Coiled stents such as Gianturco-Roubin II and Crossflex II seem to provide an easier approach to bifurcations, and are also widely used in clinical practice. In this case also (Fig. 2), the guidewires (5, 6) are placed in both vessels and both vessels (2, 3) are predilated with the help of the balloons. Then, the wire is either removed from the straightest vessel or left alone, and the stent (10) is deployed into the most angulated artery (3). Then, if it had been removed, the wire is repositioned in the straight vessel (2) and the second stent (11) is deployed there with proximal overlap of the first one (10). Although the coiled stent technique is technically less complicated, it also has crucial flaws, such as possible plaque prolapse through stent struts. Also, coiled stents without axial support may be damaged during recrossing and balloon dilation, which may lead to higher complication rates.

Yet another "Y" technique or "three-stent" (Fig. 3) includes subsequent placement and deployment of two stents (12, 13) in the two arteries (2, 3) immediately after the bifurcation, and then, using two kissing balloons with their distal parts protruding into both arteries, deployment of the third stent (14) in the segment (1) just proximal to the bifurcation. This technique provides more complete lesion coverage, while maintaining access to both vessels. However, it is more demanding (optimal predilation of the lesions,

avoiding guide wire twisting, etc.) and gaps between stents are often present.

There are more advanced technical solutions to the stenting of coronary bifurcations. One of them is "V" stenting, which ensures better positioning of the stent, and facilitates better lesion coverage (Fig. 4). After placing two guide wires into both vessels (2, 3), two stents (15, 16) are placed simultaneously on two kissing balloons with their distal parts protruding into both arteries just after the bifurcation. Then both balloons are alternately dilated to maintain correct stent position during deployment, and finally, the final expansion of the stents (15, 16) through the expansion of the balloons is performed. Therefore, this method ensures better placement of the two arms of the stent, linked together by the bridge. However, in this technique a "neo-carina" is formed (Fig. 4a) by the adjacent walls of two stents in the proximal vessel, which creates an extra turbulence in the vessel and, thus, may compromise blood flow.

Another interesting method of stenting coronary bifurcation is a "JoStent" technique (Lowe, Kumar, Roy: "New balloon expandable stent for bifurcation lesions." Catheterization and Cardiovascular Diagnosis 41:235-236, 1997). This mesh stent (17) has an uneven number of cells at various sections, 8 cells (18) at distal sections and 4 cells (19) in the middle section (Fig.5). This allows expansion to 3.5 mm within the central cells (20), permitting better passage of the guide wire and the second stent to the side branch. Implantation begins by placing the guide wires into both vessels, followed by alternate predilations. Then, the wire is removed from the side branch, and the "JoStent" (17) is placed in the main vessel. Then, through the 3.5 mm central cell (20), the guide wire is repassed to the branch, and the second stent (21) is delivered and deployed in the side branch. There are two variations of the second stent design: 1) conventional design, when the stent is deployed just distally of the bifurcation; 2) "JoStent" design, when the proximal part of the second stent is placed in the proximal vessel, overlapping the proximal part of the first stent (Fig. 6). Though this method seems to be more advanced than the previously described techniques, it either does not provide optimal coverage of the diseased vessel (variation 1), or doubles the proximal vessel wall area covered by the stent (variation 2).

Therefore, the Optimal Expandable Bifurcated Stent should posess the following characteristics:

1. Stent geometry closely corresponding to the Y-shaped anatomy of bifurcation vessels.

2. Stent geometry allowing a change in the angle between the two Y-shaped legs anywhere from 0 to 180 degress, according to the angle of the coronary artery bifurcation.

3. Optimal coverage of the bifurcation carina.

4. Maximal radial strength.

5. Flexibility according to the dynamic parameters of coronary artery bifurcation.

6. Low Profile.

7. Non-shortening on expansion.

8. Optimal expansion in the bifurcated vessel.

9. Visibility in X-rays.

10. Capability of local drug delivery.

11. Facilitation of the stenting technique of bifurcated coronary vessels.

Prior Art

There is a known "Y" Stent design presented in PCT/IL 98/00275 of June 14, '98. In this design (Fig. 7) the constructive elements, which are preliminarily formed on a thin metallic sheet surface (22) as a single Y-shaped structure, in their established form are stents (23, 24, 25) connected one to another. Each of these common stent legs includes two relatively rigid bands (26, 27), (28, 29), (30, 31) executed as a chain of consecutively attached pockets, formed by the bending of the saw-shaped profile protrusions. The closed loops, elements (34 and 35), forming the strutted rings along the longitudinal axis of the stent upon its expansion, are fastened to the saw-shaped profile bases, for example (32, 33).

In accordance with the known technique of "Y" prototype stent installation, two kissing balloons (36, 37) can be used, which are advanced in the vessel with the help of two guide wires (38, 39) as is shown in Figs. 8, 9a, 9b and 10. One of the main obstacles in the designing of such devices is providing a minimal outward diameter of the unexpanded stent located on uninflated kissing balloons, that allows free realization of the interventional procedure. Notwithstanding the fact that in the "Y" prototype stent a single

design construction is achieved, however the stent's assembled form as seen from the situation shown in Fig. 9a, is impossible, since the presented cross section (Fig. 9a) is determined by Fig. 8. Fig 8 shows uninflated kissing balloons (36, 37) at which the outward diameter is determined in general by the sizes of sufficiently rigid polymer tubes (on Fig. 8 the polymer tubes are not shown). Being pressed to each other, the said tubes cannot form an oval in accordance with Fig 9a. As a result, the sum total of the diametrical sizes including the four thicknesses of the said polymer tubes' walls, four thicknesses of the unexpanded stent lateral legs' walls, already deformed to some degree, and another four thicknesses of the oppositely located pockets formed from the rigid band's walls form a sufficiently large outward diameter, which is unacceptable for the normal device implantation into a bifurcation vessel.

The prototype "Y" Stent's dissimilar longitudinal flexibility hinders the normal delivery of the device into a bifurcation vessel, due to the non-uniform cross section of each patient's individual vascular anatomy. It would be desirable to secure a heightened flexibility of the "Y" stent legs (40, 41, 42) in all spatial directions.

The requirement of heightened longitudinal flexibility is especially important in complicated anatomical cases, where the diagonal D does not directly correspond to the "Y" stent common form, rather for example, is situated at an negative angle. In other words, the diagonal D is directed to the opposite side in relation to the blood flow from the main vessel. Performing such a bend of the "Y" prototype stent lateral leg is impossible.

The presence of pockets, where a polymer thread, loaded with therapeutic agents for local drug delivery is deployed, is a positive characteristic of the "Y" stent. However, the action of such a polymer thread will be no less efficient if this thread is deployed in the "Y" stent leg of the main vessel only. The pockets in the "Y" stent lateral legs for the proximal LAD and diagonal D need not be formed since the local pharmacological action can be achieved through the blood flow from the main vessel. Besides this, the pockets on the "Y" prototype lateral legs present a threat of adhesion to themselves, which can provoke a general negative outcome of implantation.

Still, one more drawback of the "Y" prototype stent is its incomplete use of the stent's surface (Fig. 10, pos. 40, 41, 42) at the location of the joint between the three

component devices connection (43) that does not allow for efficient covering of the bifurcation carina area with metal. Thus, the prototype "Y" stent cannot cover all the necessary area of the restored vascular channel to the full degree, and so does not fulfill the objectives of intravasculasr intervention.

Summary of the Invention

The purpose of this invention is to create a "Y" stent design with heightened flexibility in all spatial directions, with a technological possibility for the decrease of the unexpanded device's outward diameter, and a simultaneous securing of longitudinal rigidity that guarantees the preservation of the linear axial sizes upon manipulations during the whole period of intravascular intervention.

The said purpose is achieved by the fact that in the Sheet Expandable Trousers Stent, the constructive elments, preliminarily formed on a thin metallic sheet surface as a single Y-shaped structure. All the three legs of which in an established form are stents, connected one to another. Each stent includes oppositely located relatively rigid bands, with a possibility of forming chains of consecutively attached pockets, and closed loops, fastened to the said bands, forming strutted rings upons the stent's expansion. The longitudinal flexibility of the said stent legs is determined in advance according to an algorithm of breaks of the said relatively rigid bands in accordance with the bifurcation segment's anatomy.

The proposed algorithm of the sequence of breaks of oppositely located relatively rigid bands to which the closed loops are fastened comprise unions of two, four, six and other even number of said closed loops in each said rigid band.

The pattern of discontinuity of the relatively rigid band parts can be performed either in accordance with the proposed algorithm or in other different combinations determined by the required stent longitudinal rigidity.

In the proposed Sheet Expandable Trousers Stent the protrusions of the chain of consecutive pockets can be executed in a continuous form.

In the proposed Sheet Expandable Trousers Stent, in the protrusions of the said chain of consecutive pockets, closed slots can be made. The bases of the protrusions form

rigid band parts, parallel to the stent longitudinal axis.

In the proposed Sheet Expandable Trouser Stent the lateral legs can contain repeated rigid bands parts, executed only as the bases of the said pockets and the closed loops fastened to them.

The proposed Sheet Expandable Trousers Stent can contain lateral legs only, thus forming a single V-shaped structure, in the said legs of which the end strutted rings are connected by plates. The said lateral legs can be provided with pockets for the deployment in them of a polymer thread, loaded with therapeutic agents for local drug delivery.

The proposed Device for the implantation of the Trousers Stent contains two guide wires, two polymer tubes and two kissing balloons of a guiding catheter. The lateral sides of the said polymer tube, in place of the longitudinal deployment of the said balloons, are executed by a flat thinning of their cylindrical sizes in such a way that the minimal wall thickness of the said tubes in place of their thinning comprises not less than the said balloon's double walls thickness. In the assembled form, the said tubes' kissing thinned surfaces grant the unexpanded stent single Y-shaped structure oval cross section of minimal size. Where pockets are maintained on the stent legs, another side of each of the polymer tubes, parallel to the previously executed surface, is flattly thinned.

Thus, the proposed "Y" stent design is devoid of the prototype stent's drawbacks. Thanks to heightened longitudinal flexibility, more successful performance of intravascular intervention is achieved into all bifurcation segments simultaneously, regardless of anatomical peculiarities of their location on the cardiac muscle.

The proposed "Y" stent design is superior to the prototype stent due to its fundamentally smaller diametrical size in unexpanded form.

The longitudinal connection of the closed loops, by the bases of the rigid band saw-shaped profile protrusions or by the rigid band parts only, makes the linear axial size of the proposed device sufficiently stable, regardless of the deformation influence rendered on it upon expansion.

It is proposed using in the single "Y" stent design, disparate diameters of the three legs according to the bifurcation segments' diameters. The relationship of the vessel bifurcation segments' diameters, is usually no less than 2:3. Therefore, the small difference

in the vessel size diameters makes it possible to create in advance, a specific stent data base from which a variant, desirable for the interventional procedure, can be chosen according to the performed coronography results.

Additionally, the technique of implantation of a complex configuration "Y" stent design, is improved through a more rational distribution of the pocket groups.

Brief Description of Drawings

The invention is herein described with the help of examples and references to the accompanying drawings, wherein:

Fig. 1 shows the stages of "T" stenting technique execution in an example of a schematic depiction of heavy damage covering the front proximal diagonal bifurcation.

Fig. 2 shows schematically the stages of Coil Stent technique execution.

Fig. 3 shows schematically the stages of "Y" stent technique execution.

Fig. 4 shows schematically the stages of "V" stent technique execution.

Fig. 5 shows the scheme of "JoStent" Side Branch.

Fig. 6 shows schematically damage covering the bifurcation in an example of applying two "JoStents" Side Branch.

Fig. 7. shows a stencil of the strutted and outline constructive elements, which according to the prototype "Y" stent, is executed on a thin metallic sheet surface.

Fig. 8 shows the prototype "Y" stent before expansion located on uninflated kissing balloons of a guiding catheter.

Fig. 9 shows the prototype "Y" stent cross-section in accordance with Fig. 8.

Fig. 10 shows the prototype "Y" stent's initial orientation in the bifurcation.

Fig. 11 a, b, c, d, e show schematically in a graphic form the algorithm of creating sections of oppositely located rigid bands, consisting of an alternating chain of consecutively attached pockets or of the rigid bands replacing them.

Fig.11f shows schematically how, in case of need, it is possible to violate the periodicity of relatively rigid bands placement in accordance with the anatomical condition of the bifurcation segments.

Fig. 12 shows a stencil of strutted and outline constructive elements of "Y" stent

according to the invention, with a maximal longitudinal flexibility of all three stent legs, according to the algorithm in Fig. 11c.

Fig. 13 shows a stencil of strutted and outline constructive elements of "Y" stent according to the invention, with an evenly decreased longitudinal flexibility of all three stent legs according to the algorithm in Fig. 11d.

Fig. 14 shows a stencil of strutted and outline constructive elements of "Y" stent according to the invention, where the longitudinal flexibility of all three stent legs are implemented not evenly but selectively for the bifurcation carina area according to the algorithm in Fig. 11f.

Fig. 15 shows a "Y" stent, according to the invention, prior to expansion located on uninflated kissing balloons of the guiding catheter.

Fig. 16 a, b show "Y" stent cross-sections in accordance with Fig. 15.

Fig. 17 shows the "Y" stent's initial orientation in the bifurcation segments, according to the invention.

Fig. 18 shows schematically the stages of "Y" stent technique execution, according to the invention.

Specific Description

In the description of the proposed "Y" stent design a main idea of the prototype stent was used, namely, the obtaining of a voluminous cylindrical device from a thin metallic sheet (see Fig. 7). However, as distinct from the "Y" prototype stent a possibility of attaining a device with heightened flexibility is shown, which is guaranteed by a special algorithm of relatively rigid bands parts placement in any of its three functional legs.

Fig. 11a and Fig. 11b show that under the single formation of closed loops, the formation of the device is either impossible (Fig. 11a) or irrational (Fig. 11b), since, in the latter case a breaking of one of the loops takes place that leads to the instability of the stent sizes in the axial direction. Further, in Fig 11 the stages of algorithm development from a maximal longitudinal flexibility variant (Fig. 11c) to the variants of increasing relatively longitudinal rigidity (Fig. 11d, e) are schematically illustrated.

It is clearly seen from Fig 11c, that in the produced periodicity of oppositely

located relatively rigid bands parts, one protrusion (44) is consecutively uniting two closed loops (45 and 46) of the stent leg. Fig. 11d shows a constructive variant of uniting already two closed loops (47 and 48), i.e. of four closed loops by one protrusion (44). Fig. 11e shows a constructive variant of uniting three closed loops (49 and 50) i.e., of six closed loops by one protrusion (44).

With an increase in quantity of closed loops to a fragmentary unit in the stent functional legs, its longitudinal rigidity increases in a relative degree which, however, does not reach that of the prototype stent.

Fig. 11f presents an example of a non-periodical quantity of united closed loops. Thus, three closed loops (51 and 52) united by one protrusion element (44) of the relatively rigid bands, located along the edges of the stent legs, are combined with the neighboring section of loop (53) and section of loop (54), in the middle of the stent leg, i.e. in a place for example of the desired maximal longitudinal flexibility. This example shows the possibility of increasing the longitudinal flexibility on any "Y" stent section where the vessel curvature is, as a rule, heightened, and can naturally facilitate conducting procedural manipulations and the correct placement of the stent functional legs in bifurcation segments.

Fig. 12 shows a flat stencil of the future "Y" stent strutted outline constructive elements according to the invention, with a greater longitudinal flexibility according to the proposed algorithm. Here, on each stent leg (55) the closed loops (56 and 57) are periodically united by a protrusion (58) of the relatively rigid band. Therefore, the opposite breaks of the relatively rigid band are creating a structure corresponding to the algorithm in Fig. 11c, on each of the stent legs (59, main vessel, 60, proximal LAD and 61, diagonal D). Fig. 12 also illustrates the fact that in the stent leg (59) for the main vessel, saw-shaped profile protrusions (62) are made, intended for the formation of pockets and the possibility of deployment of a polymer thread loaded with therapeutic agents for local drug delivery. It is also seen here that each saw-shaped profile protrusion (62) has a closed slot, the bases of which form sections of one rigid band. This avoids the stretching of the saw-shaped protrusions (62) in the axial direction upon the stent's expansion. It is supposed that the local therapeutic action of the polymer thread loaded with medical agents is able to serve all three vessel segments along the blood flow and

therefore, there is no need to make pockets along the stent side legs for proximal LAD and diagonal D, replacing them by rigid band (63) sections.

Fig. 13 shows the same as Fig. 12 with relatively even longitudinal flexibility of the legs of the future "Y" stent (64), according to the invention, realized according to the algorithm in Fig. 11d.

Fig. 14 shows the same as Fig. 12, where the longitudinal flexibility of the legs of the stent (65), according to the invention, is uneven but increased only on those stent segments that are located in the bifurcation carina area due to the execution of breaks (66 and 67) of the relatively rigid bands in the leg for the main vessel and breaks (68, 69), (70, 71) in the side legs for proximal LAD and diagonal D, accordingly.

Fig. 15 shows the location of the legs of the "Y" stent (72), according to the invention, on uninflated kissing balloons (73 and 74) in a three dimensional image. Position (75) marks one of the closed loops (main vessel), while positions (76 and 77) mark the closed loops of the legs of the stent (proximal LAD and diagonal D).

Fig. 16 a, b show two cross-sections in accordance with Fig. 15, on which two guide wires (78), two polymer tubes (79), two balloons (80, 81), side legs (82, 83) and pockets (84) of the stent main leg (85) are marked. Position (86) shows polymer tubes (79) kissing surfaces on both cross-sections (Fig. 16) executed by the thinning of the cylindrical sizes for the creation of the minimal size oval cross-section of the unexpanded stent single Y-shaped structure.

Fig. 17 shows a general scheme of the three "Y" stent legs' simultaneous introduction into bifurcation segments. Position (87) marks guide wires, position (88), a balloon and position (89), a stent side leg, for the implantation into proximal LAD, position (90), a balloon and position (91), a stent side leg for the implantation into diagonal D, as well as stent design element (92) intended for the introduction into the main vessel.

The technique "Y" stent implantation for covering the bifurcation lesion includes the following steps. Before implantation, the "Y" stent is located on two kissing balloons (80, 81), and has a cross section of minimal oval form (Figs. 15, 16). First, according to the known technique (Fig. 18a) two guide wires (78) are introduced into proximal LAD and diagonal D. Then, the kissing balloons are placed across the bifurcation area and

predilation is performed. The stent is delivered to the target area and deployed into the main vessel. The stent is placed in the bifurcation area in such a way that the pockets of the main leg of the stent should turn out to be in the geometrical axes of the intersectional plane of proximal LAD and diagonal D. This allows the legs of the stent for proximal LAD and diagonal D to open freely and form an angle between themselves and easily move in the bifurcation vessel. Additionally, due to the stent's minimal outward surface oval form cross-section and high flexibility along the corresponding geometrical axes of the bifurcation segments, the free angle variation insures the necessary spatial orientation of the device in the vessel and optimal anatomic position before expansion (18b). By the alternate inflation of the kissing balloons, the legs of the stent are expanded in proximal LAD and diagonal D, and then, by the simultaneous inflation of the same balloons in the main vessel (Fig. 18c). The implanted stent covers the bifurcation lesion as a whole, and does not violate the vessel's natural dynamics upon contraction of the cardiac muscle. This creates the most favorable conditions for the optimal reconstruction of the traumatized vascular tissue.

The linear axial size of the stent legs could be disparate depending on the sizes and location of the lesion in the bifurcation vessel. The length of the stent leg for the main vessel can be minimized to be comprised of a single pair of closed loops, or be absent completely, while the left stent side legs remain connected to each other and become a V-shaped structure. In this case, the pockets for the deployment of a polymer thread carrying therapeutic agents can be located on the stent's side legs.

Thus, the proposed "Y"stent resolves several main problems of modern interventional cardiology.

1. The achieved single Y-shaped stent design structure contributes to the simplification of the technique and decreases trauma in the stenting procedure due to the single mechanical action on the vessels.

2. The obtained diminishing of the stent design minimal diametrical size in the unexpanded state allows the fulfillment of the complex procedure of stent implantation in a bifurcation vessel and decrease trauma to the vessels.

3. The proposed algorithmic connection of closed loops (strutted rings) allows the realization of greatest longitudinal flexibility, directly in places determined by the

anatomical peculiarities of bifurcation segments.

4. An additional merit of the stent design consists in the possibility of the metal coating of the bifurcation carina area that should contribute to the more effective treatment of the lesion in that vessel segment and to the generally more favorable outcome of intravascular intervention.

*

What is claimed is:

1. The Sheet Expandable Trousers Stent and Device for its Implantation for insertion in a lumen of bifurcation segments of a living being, comprising:

-constructive elements, preliminarily formed on a thin metallic sheet as a single Y-shaped structure with all three legs in an established state being stents connected to each other, including oppositely located relatively rigid bands with a possibility of forming chains of consecutively attached pockets on them and closed loops fastened to the said bands, that form strutted rings upon the stent's expansion, whereas the longitudinal flexibility of the said stent legs is determined in advance according to an algorithm of breaks of the relatively rigid bands in accordance with the anatomy of the bifurcation segments;

-the break sequence algorithm of the oppositely located rigid bands, to which the closed loops are fastened, comprise unions in each said rigid band of two, four, six and other even numbers of the said closed loops;

-the discontinuity of the relatively rigid band parts is performed either in accordance with the said algorithm or in other different combinations, determined by the required longitudinal rigidity of the said stent.

2. The Sheet Expandable Trousers Stent as in claim 1, with the protrusions of the chain of consecutively attached pockets fulfilled in a continuous form.

3. The Sheet Expandable Trousers Stent as in claims 1, 2, which has in the said protrusions closed slots, the bases of which, form rigid band parts parallel to the longitudinal axis.

4. The Sheet Expandable Trousers Stent as in claims 1, 2, 3, Y-shaped structure, whose legs contain oppositely repeating rigid bands parts fulfilled only as the bases of the said pockets and closed loops fastened to them.

5. The Sheet Expandable Trousers Stent as in claims 1, 2, 3, 4, containing only the

stent's lateral legs, forming a single V-shaped structure, in the said legs of which the end strutted rings are connected by plates, whereas the said stent lateral legs are provided with pockets for the deployment of a polymer thread loaded with therapeutic agents for local drug delivery.

6. Device for implantation of the Sheet Expandable Trousers Stent as in claims 1, 2, 3, 4, 5, containing two guide wires, two polymer tubes, and two kissing balloons of the guiding catheter, in which the said polymer tubes' lateral sides at the place of longitudinal deployment of the said balloons are made flat through the thinning of their cylindrical sizes so that the minimal thickness of the said tubes walls, at the location of their thinning, comprises no less than double thickness of the said balloon's walls, whereas in an assembled form the kissing thinned surfaces of the said tubes grant the minimal sized oval cross-section of the unexpanded single Y-shaped stent structure, and where pockets are preserved on the stent's legs, in each said polymer tube one more lateral side, parallel to the previously executed surface on the said polymer lateral side, is thinned on the surface.

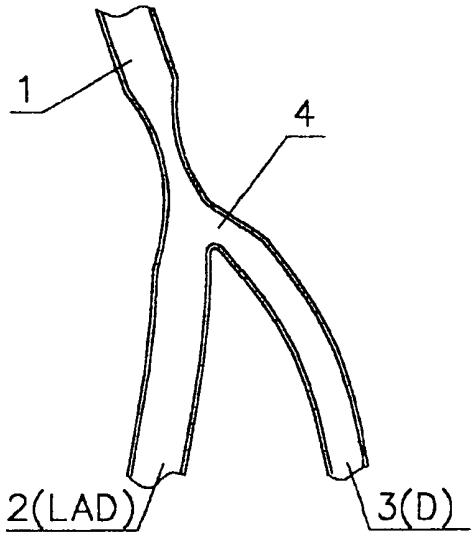

Fig.1a

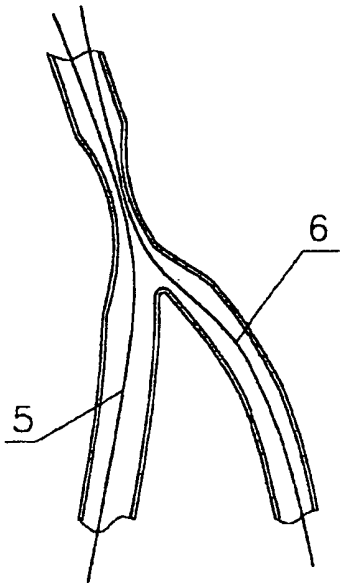

Fig.1b

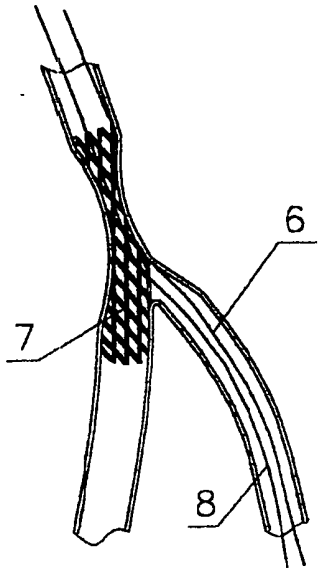

Fig.1c

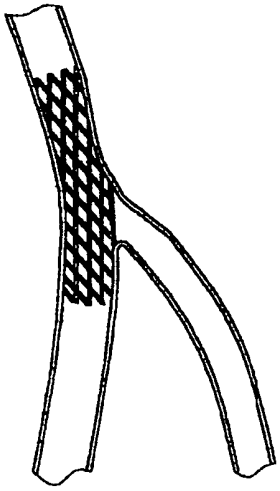

Fig.1d

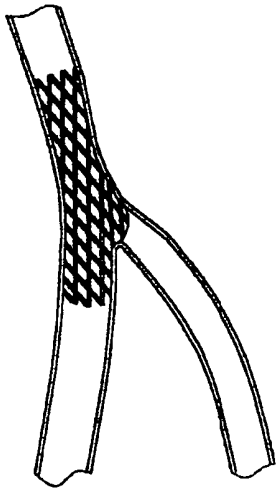

Fig.1e

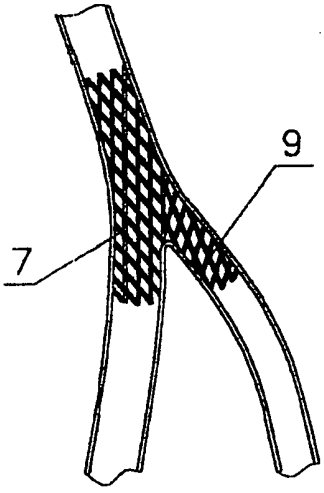

Fig.1f

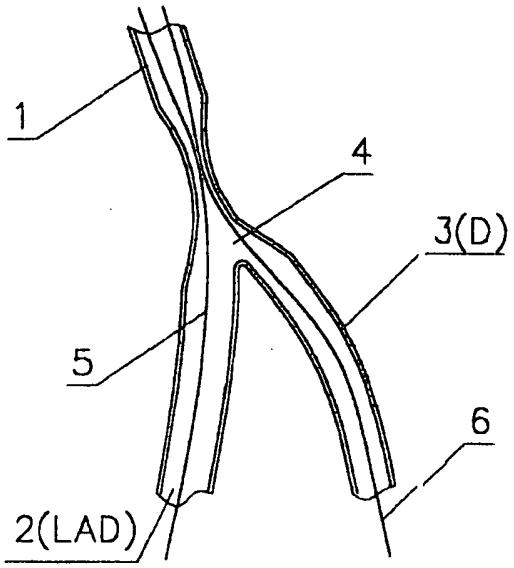

Fig.2a

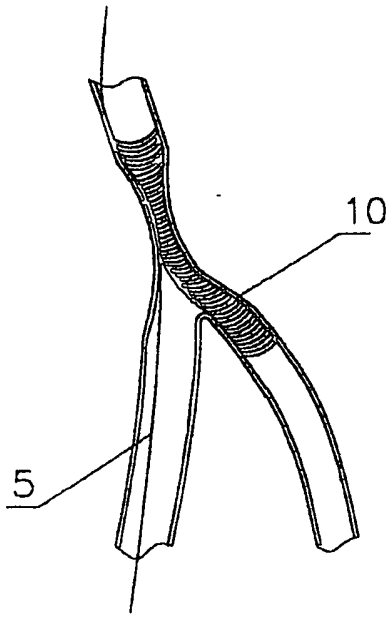

Fig.2b

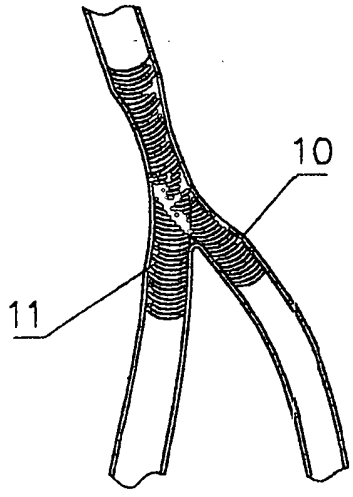

Fig.2c

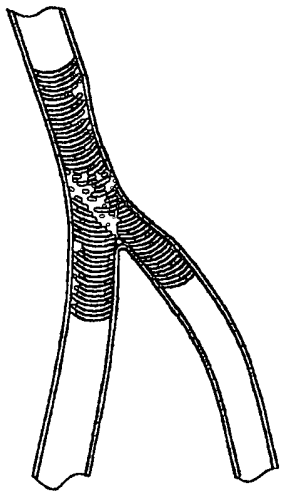

Fig.2d

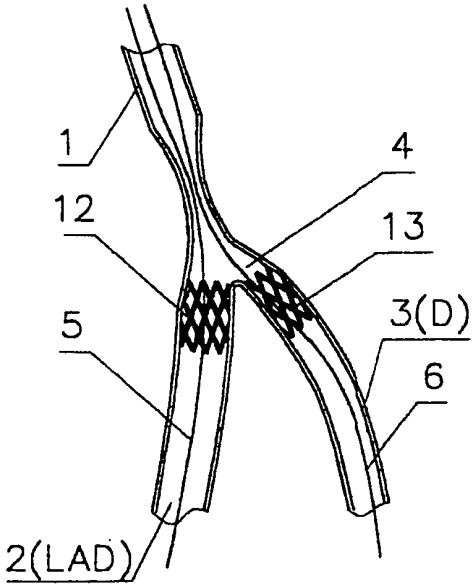

Fig.3a

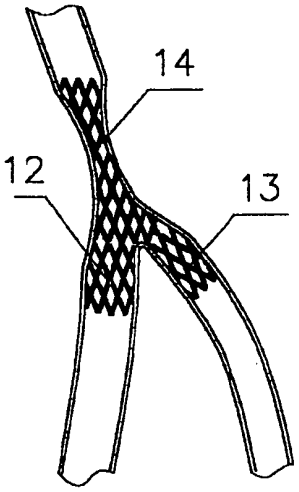

Fig.3b

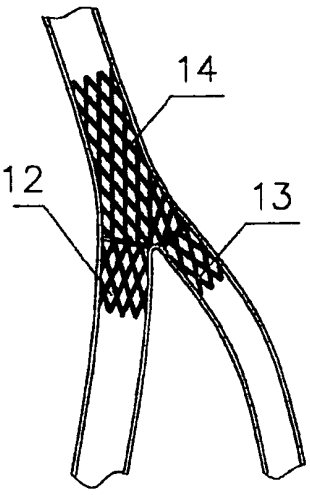

Fig.3c

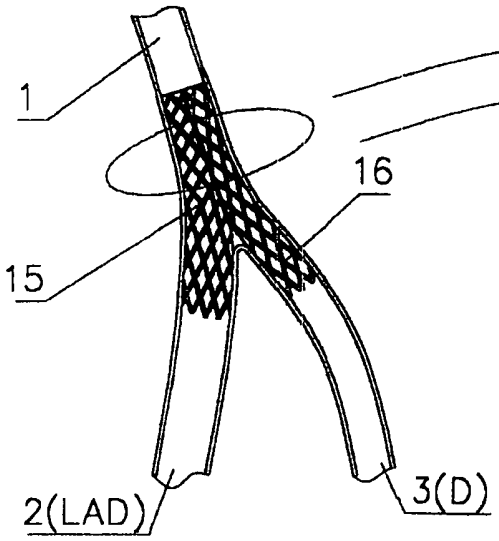

Fig.4a

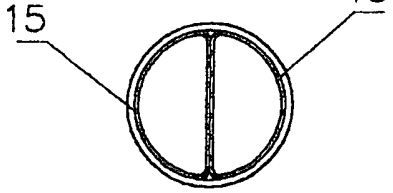

Fig.4b
scaled

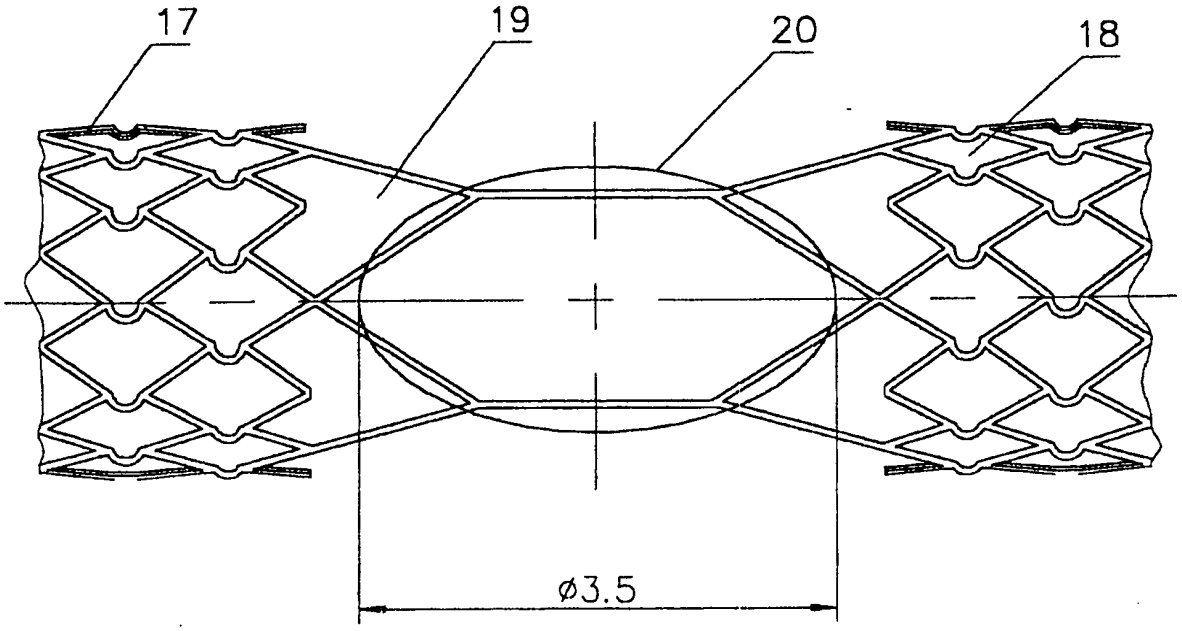

Fig.5

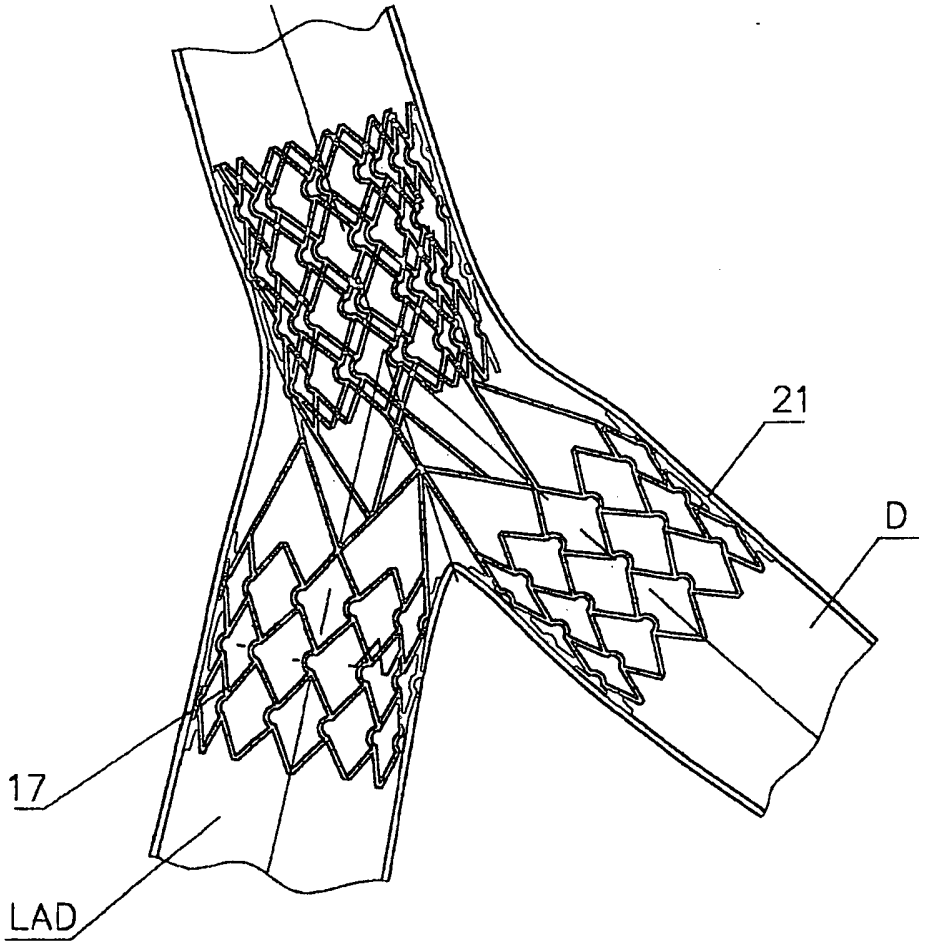

Fig.6

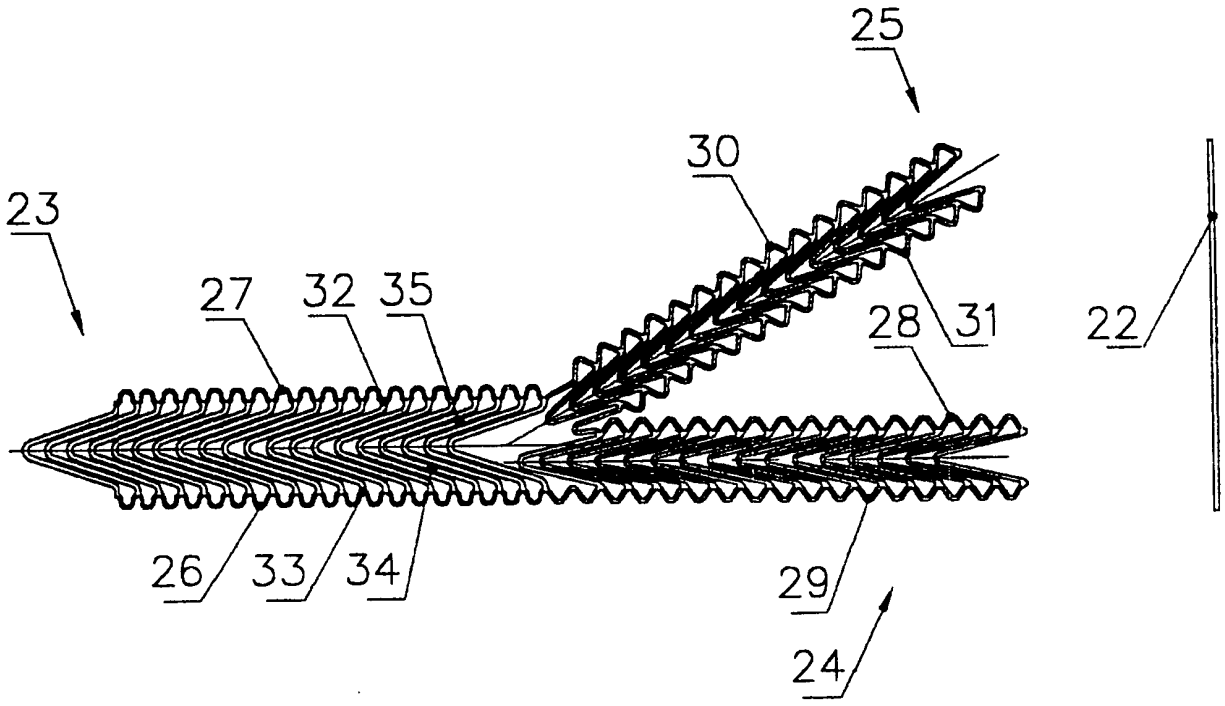

Fig.7

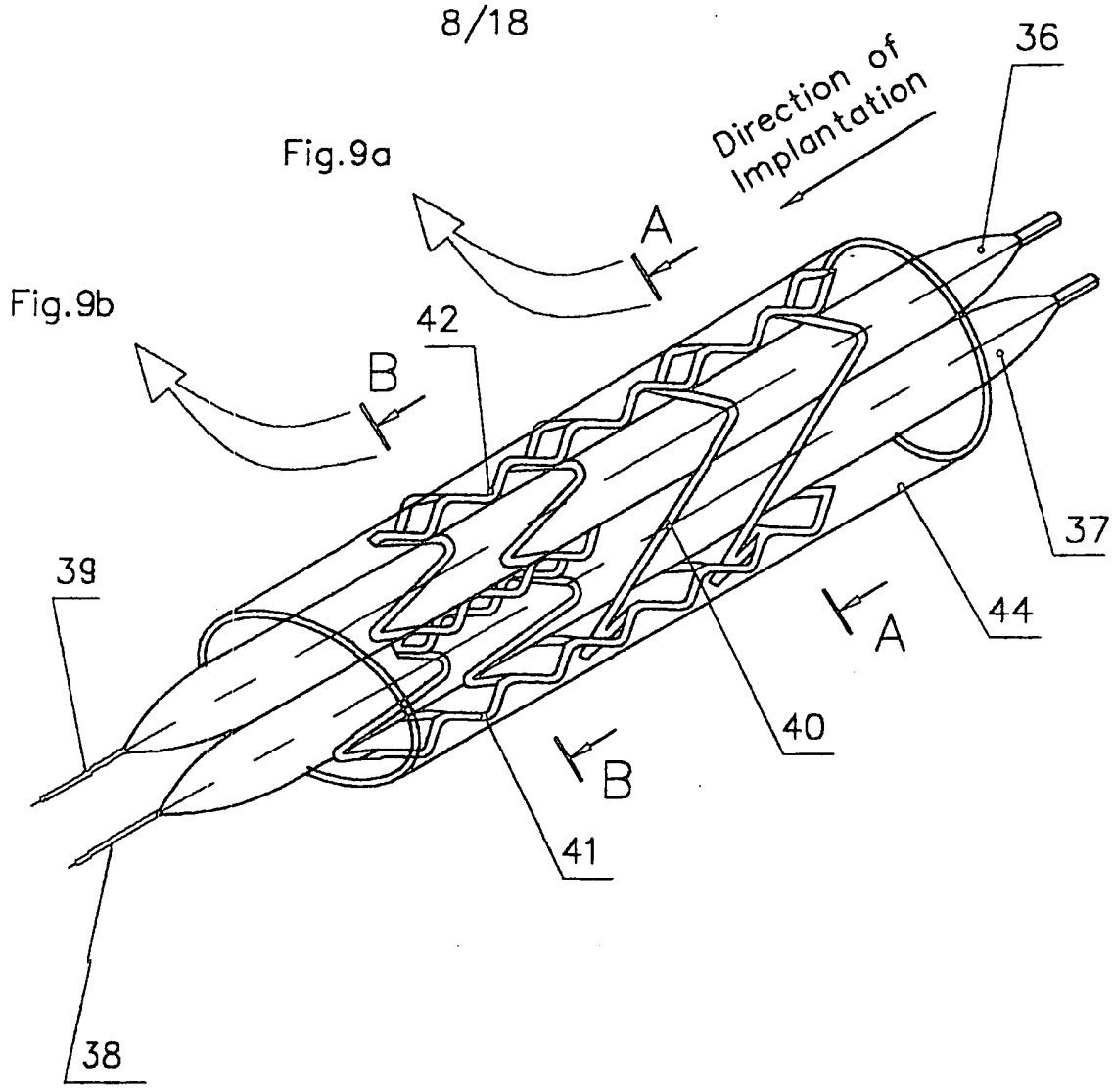
Direction of Implantation
36
Fig.9a
A
Fig.9b
B
42
37
39
A
44
40
B
41
38

Fig.8

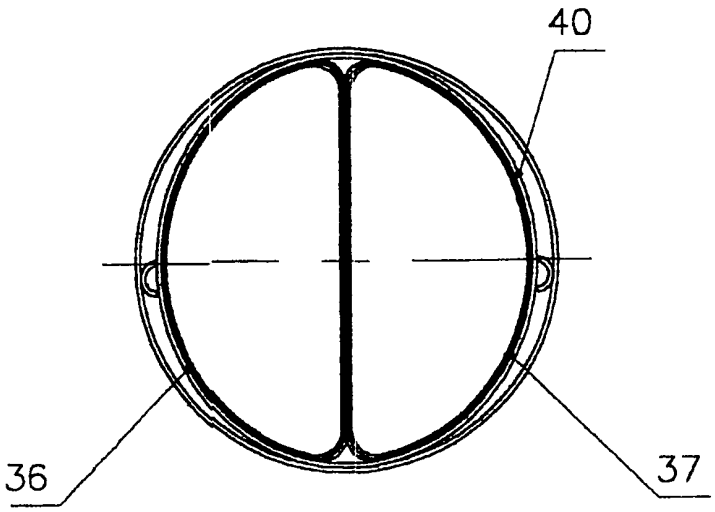

Fig.9a

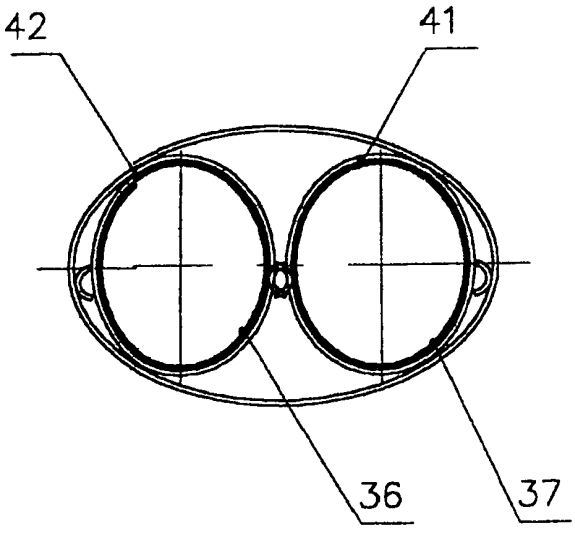

Fig.9b

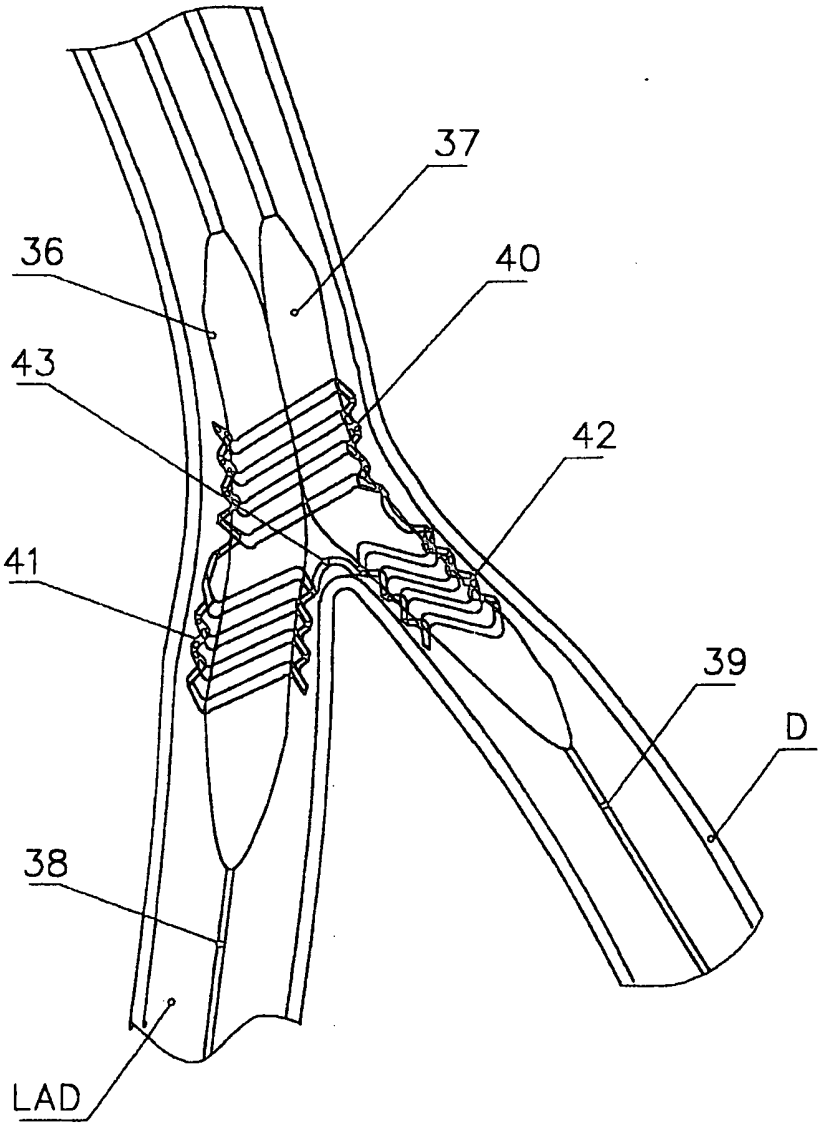

Fig.10

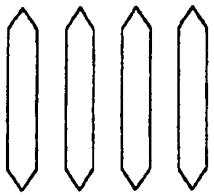

Fig.11a

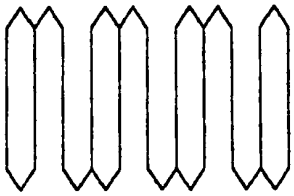

Fig.11b

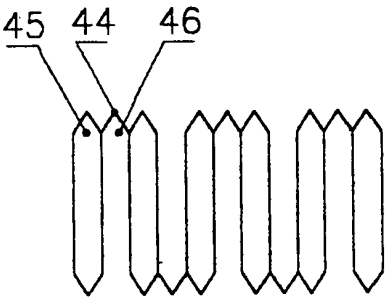

Fig.11c

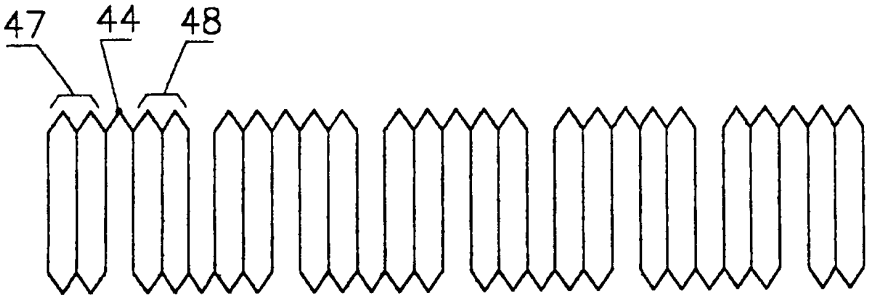

Fig.11d

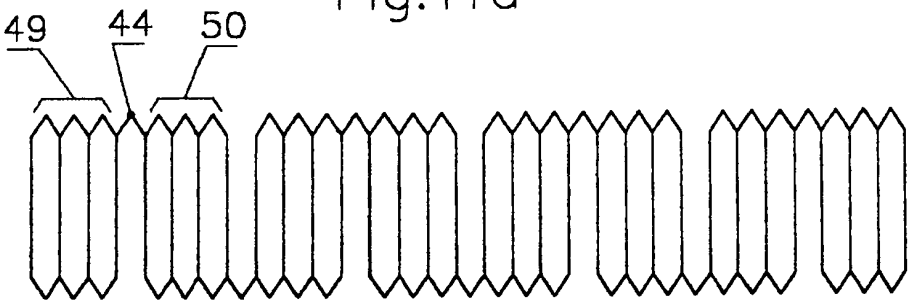

Fig.11e

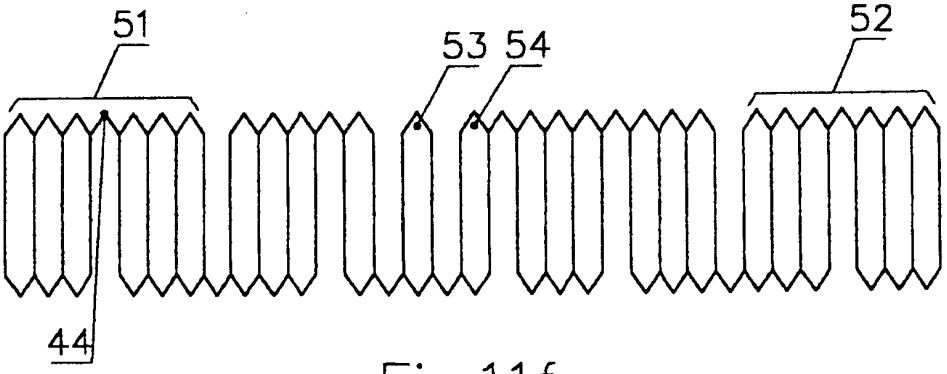

Fig.11f

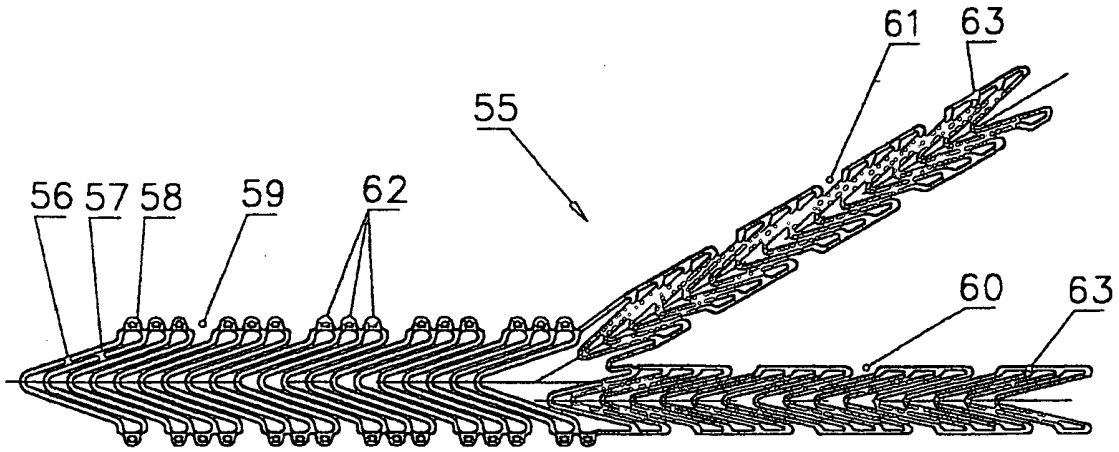

Fig.12

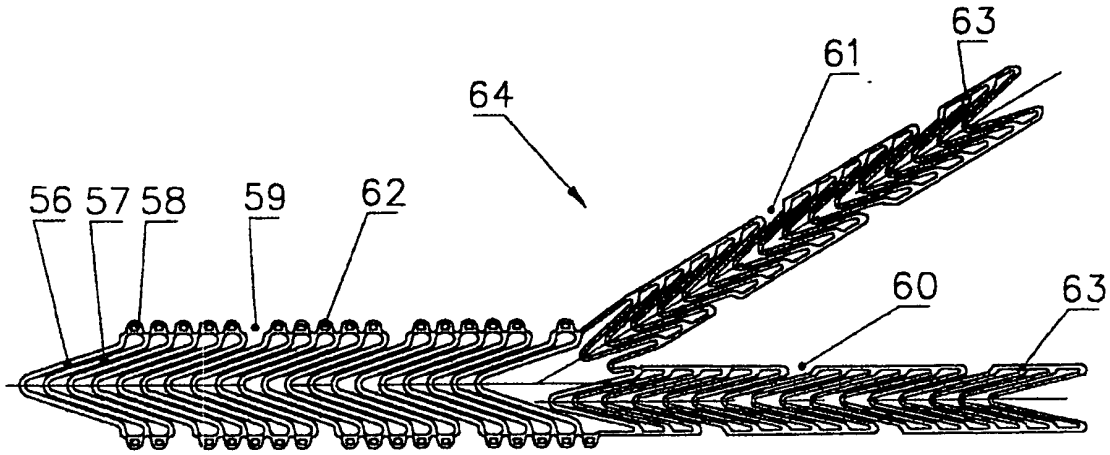

Fig.13

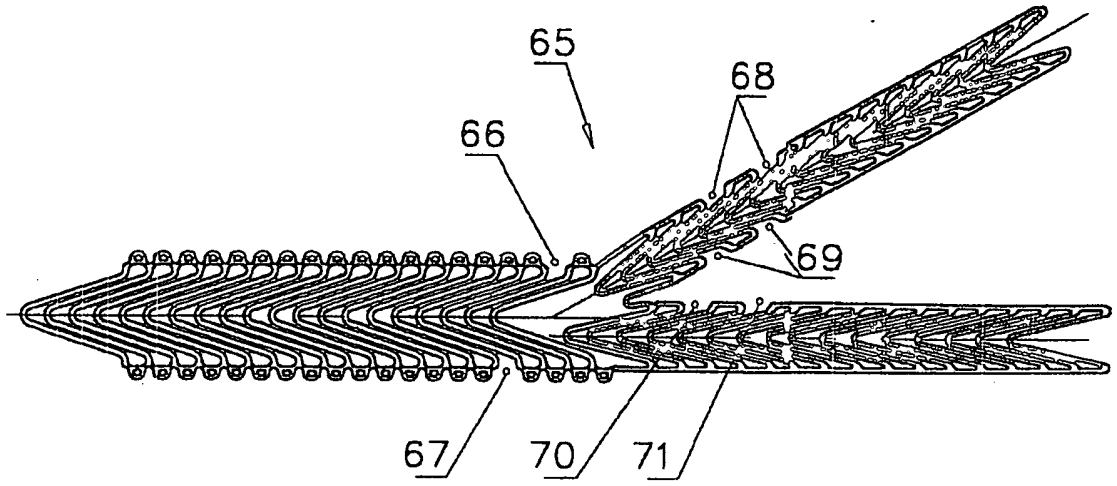

Fig.14

Fig.16a

Fig.16b

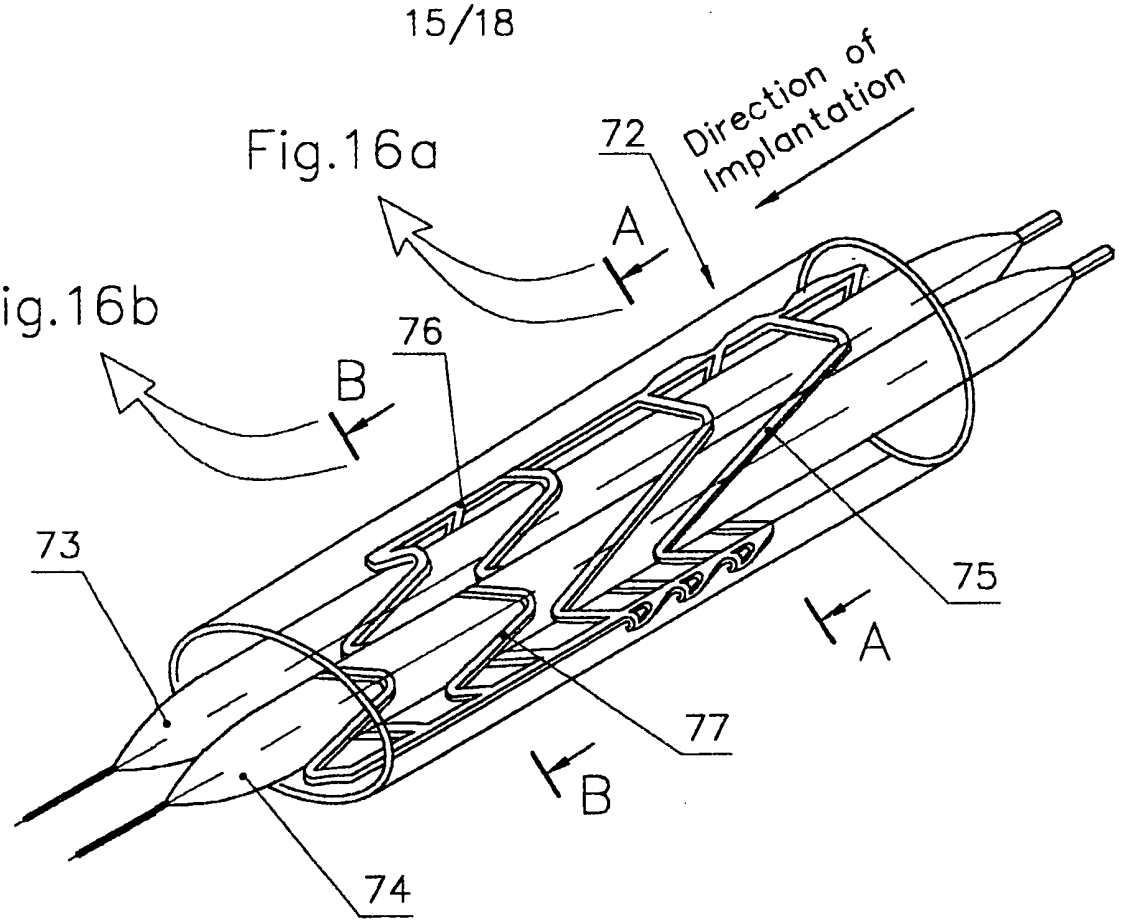

Fig.15

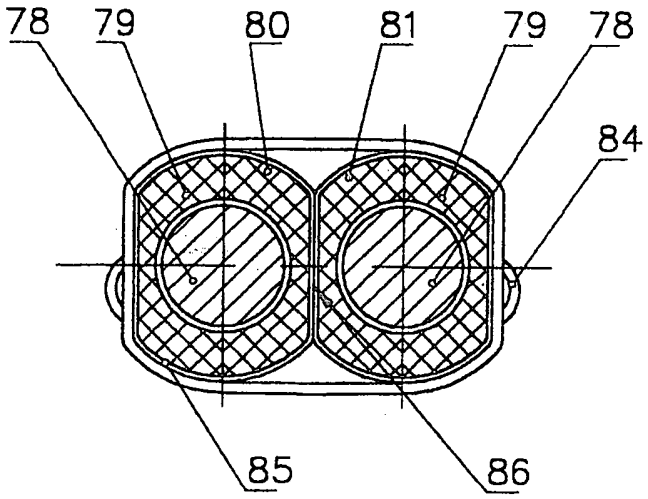

Fig.16a

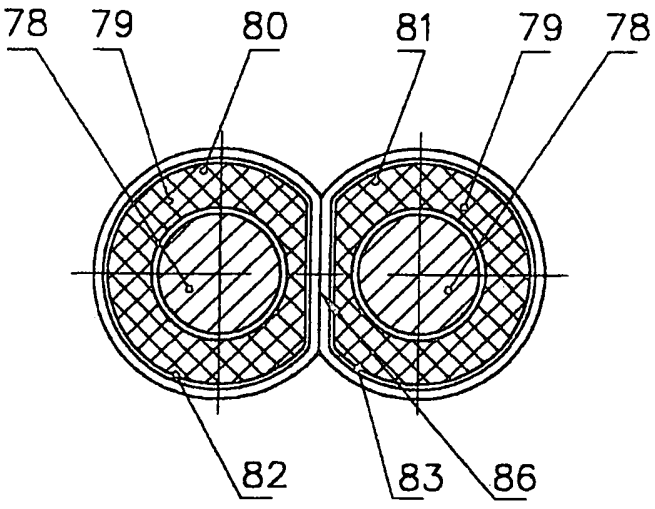

Fig.16b

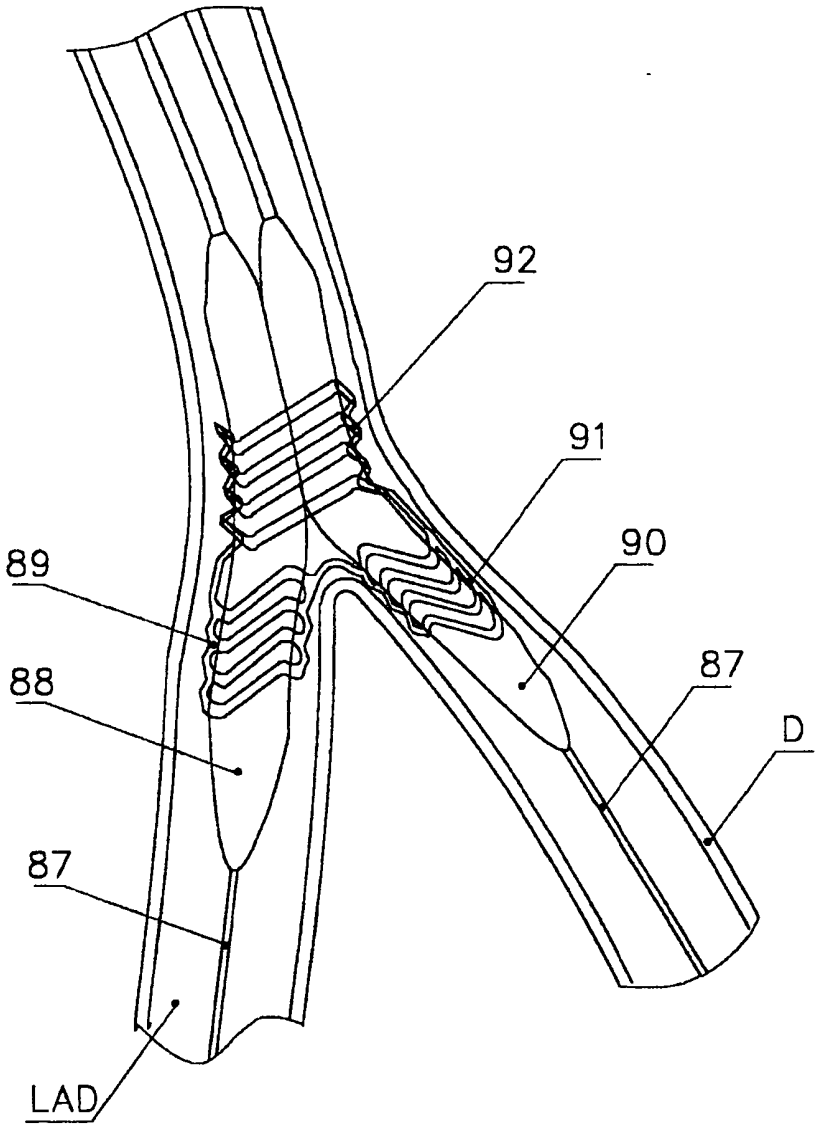

Fig.17

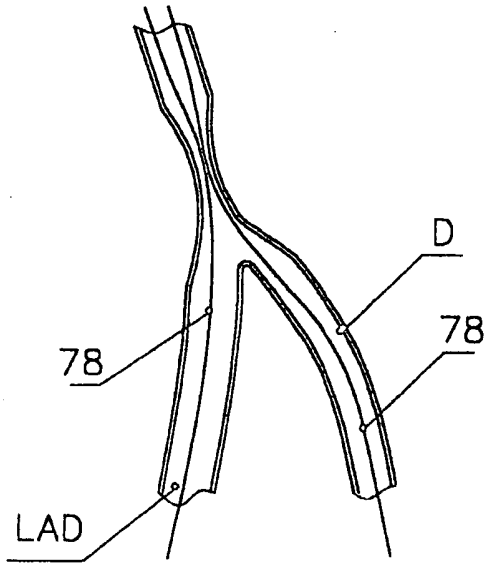

Fig.18a

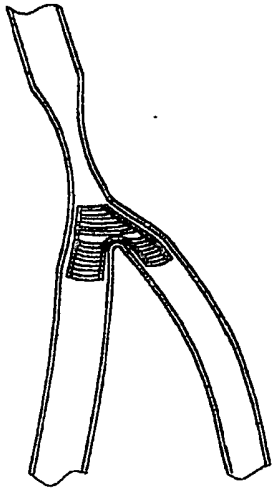

Fig.18b

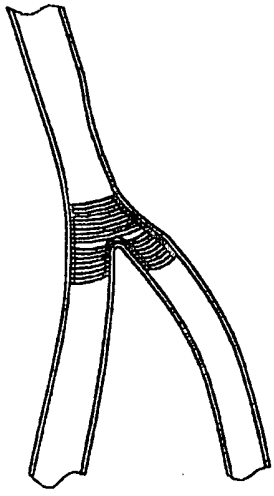

Fig.18c

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00541

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL :623/1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/192, 194; 623/1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,649,977 A (CAMPBELL) 22 June 1997, entire document. Teaches a stent formed from a sheet of material.	1-6
A	US 5,800,526 A (ANDERSON et al) 01 September 1998, entire document.	1-6
A	US 5,810,872 A (KANESAKA et al) 22 September 1998, entire document.	1-6
A, E	US 5,836,964 A (RICHTER et al) 17 November 1998, entire document. Stent formed form a sheet of material.	1-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 JANUARY 1999	Date of mailing of the international search report 04 MAR 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer BRUCE SNOW Telephone No. (703) 308-3255

Form PCT/ISA/210 (second sheet)(July 1992)★